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PCT INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 116055/BAL	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
International Application No. PCT/AU2003/001288	International Filing Date (day/month/year) 30 September 2003	Priority Date (day/month/year) 30 September 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ H01R 43/00, A61N 1/05		
Applicant COCHLEAR LIMITED et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 13 February 2004	Date of completion of the report 18 January 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer DALE SIVER Telephone No. (02) 6283 2196

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU2003/001288

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

The ISR covered all the claims, because little additional effort was required.

The groups of claims identified in the ISR are;

1 Claims 1-30 for a method of forming an electrically conducting feedthrough with steps characterised by a conductive structure with sacrificial and non-sacrificial components.

2. Claims 31-33 for a feedthrough formed from a film or shim of an electrically conductive metal or alloy.

3. Claims 34-50

The characterising portions of independent claims 34, 35, 36, 37, 40 include a feedthrough with an insulating layer, conductive members with ends and variations to the geometry of the conducting members.

As the only feature common to these groups of claims is the "feedthrough", and it is admitted that a feedthrough per se is already known, the claims lack unity a priori.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
- ☐ the parts relating to claims Nos.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU2003/001288

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-50	YES
	Claims	NO
Inventive step (IS)	Claims 1-30,32,33,38-39,41-50	YES
	Claims 31,34-37,40	NO
Industrial applicability (IA)	Claims 1-50	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

- D1 US 6414835 B1 (WOLF et al.) 2 July 2002
D2 US 6336269 B1 (ELDRIDGE et al.) 8 January 2002
D3 ROUSCHE P.J. et al. "Flexible Polyimide-Based Intracortical Electrode Arrays with Bioactive Capability" IEEE Trans. On Biomedical Engineering, Vol. 48, No. 3 March 2001

Novelty (N)

None of the citations on their own disclose each and every integer of the claims.

More particularly claim 1 is novel because none of the citations disclose a method of forming a feedthrough using a **sacrificial component** and a non-sacrificial component followings the steps i) to (iii) in the claim. The prior art identified in the search use a combination of micromachining, deposition and/or etching. Some prior art uses a conducting sacrificial layer but no coating step of the non-sacrificial layer with an insulator in the order specified in the claim.

Inventive step (IS)

D1 discloses a multi-electrode feedthrough using screen printing of the electrodes. D3 discloses polyimide-based intracortical electrode arrays with gold (platinum or iridium may be used as well) electrode surfaces. Claim 31 lacks an inventive step when D1 or D3 is combined with common general knowledge in the art of feedthrough manufacture.

D2 discloses a non-linear feedthrough. Claim 34 lacks an inventive step when D2 is combined with common general knowledge in the art of feedthrough manufacture. Claims 34-37 and 40 also lack an inventive step when D1 is combined with either D2 or D3.

Industrial applicability (IA)

The present application contains disclosures of a method and apparatus that has an industrial application

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. All of the claims (except perhaps claim 50) are not fully supported by the description because they fail to fully define the described apparatus and method. The description is concerned with a method of making an implantable electrode and feedthrough. Moreover it appears essential that the feedthrough is hermetically sealed. There is no support for the broad claims that fail to include these essential features.